510(k) Summary

Submitted By: Toby Orthopaedics
401 SW 42nd Ave, Suite 200
Miami, FL 33134 USA
Phone: (866) 979-8629
Fax: (305) 768-0269

NOV 04 2013

Contact Name: Eric Neyhard

Date Prepared: June 18th, 2013

Trade Name: WOLF® Long Bone Plate System

Common Name: Bone Plate

Classification: 21 CFR 888.3030 – Single / multiple component metallic bone fixation appliances and accessories

Predicate Devices: Synthes LCP System – K082807
Synthes 1/3 Tubular DCL Plate – K011335
Acumed Congruent Bone Plate System – K012655, K102998

Device Description: The TOBY® WOLF® Long Bone Plate system consists of implantable titanium alloy bone plates and fasteners used for the repair of fractures, osteotomies, and non-unions of upper extremity diaphyses. The system includes specialized stainless steel instrumentation that is provided to assist with the installation of the bone plates and fasteners.

Intended Use: The WOLF® Long Bone Plate system is indicated for fractures, osteotomies, and non-unions of upper extremity diaphyses.

Technological Characteristics: A comparison of the technological characteristics and performance characteristics of the WOLF® Long Bone Plate system and the predicate devices was performed. The devices were found to be substantially equivalent.

Performance Data:

The TOBY® WOLF® Long Bone Plate system complies with the requirements of listed FDA Recognized Consensus Standards.

- ASTM F136-12a, Standards Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
- ASTM F899-12b, Standard Specification for Wrought Stainless Steels for Surgical Instruments

The implantable and tissue contact materials used to fabricate the WOLF® Long Bone Plate system components have a long history of safe usage in medical devices. The materials of construction are safe and effective, and similar to those used in the predicate device system.

Substantial equivalence is demonstrated between the TOBY® WOLF® Long Bone Plate system and the predicate device systems listed above through the review of various performance data. Substantial equivalence has been determined through a 20-point comparison of technological features and a multi-parameter comparison of mechanical performance. The design features are similar in the device systems, as are the indications for use. Results from stiffness, strength and fatigue testing per ASTM F382-99, and screw pullout testing, demonstrate that the WOLF® Long Bone Plate system is safe and effective, and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 4, 2013

TOBY ORTHOPAEDICS
Mr. Eric Neyhard
Chief Operating Officer
1805 Ponce de Leon Boulevard, Suite 501
Coral Gables, Florida 33134

Re: K131834
Trade/Device Name: WOLF® Long Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Date: October 3, 2013
Received: October 4, 2013

Dear Mr. Neyhard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TOBY ORTHOPAEDICS

Indications For Use

510(k) Number (if known): K131834

Device Name: WOLF® Long Bone Plate System

Indications For Use: The WOLF® Plate system is indicated for fractures, osteotomies, and non-unions of upper extremity diaphyses.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices